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| 09/633,364 | 08/07/2000 | John Fikes | 18623014710 | 3960 |

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|---|---|
| RAWLINGS, STEPHEN L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/633,364 | FIKES ET AL. | |
| | Examiner | Art Unit | |
| | Stephen L. Rawlings, Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *114,124,125,127,129-131,133-137,139,140,215 and 230-233* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *114,124,125,127,129-131,133-137,139,140,215 and 230-233* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20041217*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. The amendment filed December 17, 2004 is acknowledged and has been entered. Claims 121-123, 126, and 128 have been canceled. Claims 114, 124, 125, 130, 131, 133, 135-137, 139, and 140 have been amended. Claims 231-233 have been added.

2. Claims 114, 124, 125, 127, 129-131, 133-137, 139, 140, 215, and 230-233 are pending in the application and are currently under prosecution.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Information Disclosure Statement*

4. The information disclosures filed November 13, 2002 and July 10, 2003 have been considered. An initialed copy of the PTO Form-1449 filed December 17, 2004, which was originally submitted July 10, 2003, is enclosed. An initialed copy of the form filed November 13, 2002 was attached to the previous Office action mailed June 17, 2004.

### *Grounds of Objection and Rejection Withdrawn*

5. Unless specifically reiterated below, Applicant's amendment filed December 17, 2004 has obviated the grounds of objection and rejection set forth in the previous Office action mailed June 17, 2004.

### *Grounds of Rejection Maintained*

***Claim Rejections - 35 USC § 112***

6. The rejection of claims 125, 130, 135-137, 139, 140, 215, 230-233 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This ground of rejection is set forth in section 12 of the Office action mailed June 17, 2004, beginning at page 5.

At pages 12-19 of the amendment filed December 17, 2004, Applicant has traversed this ground of rejection.

Applicant's argument has been carefully considered but not found persuasive for the following reason:

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

Applicant has argued that the disclosure of the amino acid sequence set forth as SEQ ID NO: 6827 as the common structural feature of the claimed invention satisfies the written description requirement. In reply, the claims have been given the broadest reasonable interpretation and are therefore drawn to a genus of peptides and proteins that vary substantially in both structure and function. Although the members of the genus comprise SEQ ID NO: 6827, this amino acid sequence does necessarily correlate with any particularly identifying functional feature that is shared by at least most members of the genus. Accordingly, the peptide of SEQ ID NO: 6827 is not representative of the genus, as a whole, nor would its description suffice to adequately describe the genus, such that the skilled artisan could immediately envision, recognize or distinguish its members from other peptides and proteins. Therefore, the supporting disclosure would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Beginning at page 17, Applicant has argued, for example, that the addition of amino acids to a peptide otherwise consisting of SEQ ID NO: 6827 does not necessarily

affect its function. In reply, the claimed invention does not necessarily have any particular function. Therefore, it could not be determined if the additional of amino acids to a peptide otherwise consisting of SEQ ID NO: 6827 alters that function. Again, in the absence of a detailed description of at least a substantial number of the members of the claimed genus of peptides and proteins, and further absent an adequate description of a representative number of those members, the skilled artisan could not immediately envision, recognize or distinguish the members of the genus.

7. The rejection of claims 114, 124, 125, 127, 129-131, 133-137, 139, 140, 215, and 230-233 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This ground of rejection is set forth in section 13 of the Office action mailed June 17, 2004, beginning at page 9.

At pages 19-22 of the amendment filed December 17, 2004, Applicant has traversed this ground of rejection.

Applicant's argument has been carefully considered but not found persuasive for the following reason:

At page 20, Applicant has remarked that it appears that this ground of rejection is solely based upon the "how to use" arm, as opposed to the "how to make" arm, of the enablement requirement set forth under 35 U.S.C. § 112, first paragraph. To the contrary, however, given the inadequacy of the supporting disclosure to describe the claimed genus, it is implicit that the skilled artisan cannot make at least most of the peptides and proteins, or compositions thereof, that are encompassed by the claims simply because one cannot make that which has not been adequately described. While the skilled artisan can "make" large numbers of peptides and proteins that comprise the amino acid sequence of SEQ ID NO: 6827, the skilled artisan cannot known which, if any, of this multitude are capable of eliciting an immune response that correlates with tumor clearance. Again, none of the claimed peptides or proteins, including the peptide

consisting of SEQ ID NO: 6827 have been shown to elicit an immune response that correlates with tumor clearance. The previous Office action states, for example, "short of making each and every one of the peptides or proteins, or the compositions thereof, which are encompassed by the claims, and empirically determining whether the peptide binds HLA-A2.1 and is capable of stimulating CTL clones that effectively lyse prostate tumor cells to provide tumor clearance, the skilled artisan could not make and use the claimed invention" (page 11, paragraph 1). As evidenced by Schoel et al., Andersen et al., and Feltkamp et al. (all of record), the art is unpredictable and absent a showing that the peptide of SEQ ID NO: 6827 is capable of stimulating an immune response that correlates with tumor clearance, the skilled artisan cannot make or use the claimed invention without first performing the undue experimentation necessary to determine whether the peptide of SEQ ID NO: 6827 can be used in the manner asserted. Furthermore, at pages 13 and 14, the previous Office action further states the specification fails to teach how to make a peptide comprising SEQ ID NO: 6827, which comprises other amino acid sequences and which can be used in the same manner as the peptide consisting of SEQ ID NO: 6827. Therefore, in response to Applicant's remarks, the provisions set forth under 35 U.S.C. § 112, first paragraph, require the supporting disclosure to sufficiently enable the skilled artisan to make and use the claimed invention; in this instance, the specification asserts that the claimed invention can be used in a number of ways, so in order to meet the requirement, the supporting disclosure must be sufficient to enable the skilled artisan to *make* peptides and proteins, or compositions thereof, that can be used in these ways.

Beginning at page 20, paragraph 4, Applicant has argued that the specification teaches the claimed invention can be used in various *in vitro* assays, such as inducing a specific CTL response *in vitro* as well as measuring the CTL response from, e.g., patients, as exemplified in Examples 16 and 17. This issue has been addressed at page 11, paragraph 2, of the previous Office action. Again, none of the claimed peptides or proteins, including the peptide consisting of SEQ ID NO: 6827 have been shown to elicit an immune response that correlates with tumor clearance. The fact that peptides and proteins encompassed by the claims can be used in studies (e.g., various

*in vitro* assays) to determine *if and how* the peptides and proteins can be used is not at issue. However, apart from using the claimed invention in studies to determine if and how the claimed invention can be used, the supporting disclosure is not sufficient to enable the skilled artisan to make and use the claimed invention in any specific manner without undue experimentation. Moreover, unless and until it is determined that the claimed peptides and polypeptides, or compositions thereof, can be used in some such specific manner (e.g., to stimulate an immune response that correlates with tumor clearance), the skilled artisan would not accept the assertion that the claimed invention can, or should be used, for example, to assess the immune response in patients.

At page 21 of the amendment, Applicant has argued the claimed invention can be used to determine whether a patient's immune system recognizes the claimed invention, because if it does, the claimed invention may potentially be used to increase the patient's immune system's response to the claimed invention; and if it does not, then the claimed invention may be used to "break tolerance" and induce an immune response to the claimed invention. Again, none of the claimed peptides or proteins, including the peptide consisting of SEQ ID NO: 6827 have been shown to elicit an immune response that correlates with tumor clearance. As proverbially expressed in the previous Office action, to use the claimed invention in such a manner, is "putting the cart before the horse". Furthermore, the specification does not teach how the claimed invention can somehow be used to break immune tolerance to the claimed invention in a patient lacking cytotoxic T lymphocytes (CTL) that bind the claimed invention.

At page 21, Applicant has argued that undue experimentation would not be required to "identify whether a given peptide claimed herein would have the requisite binding and/or immunogenicity for desired use, given that the methodology that would be used to do so is well known and conventional in the art. The art, however, is unpredictable; one skilled in the art cannot reliably and accurately predict which peptides and proteins encompassed by the claims can be used in a specific manner. Upon careful consideration of each of the factors used to determine whether undue experimentation is required, in accordance with *Ex parte Forman*, 230 USPQ 546 (BPAI 1986), the preponderance of factual evidence of record indicates that the amount of

guidance, direction, and exemplification disclosed in the specification would not be sufficient to enable the skilled artisan to use the claimed invention without undue amount experimentation.

At page 22, Applicant has argued that some non-working embodiments of the claimed invention are acceptable, since the working embodiments can be identified using assays. In response, none of the claimed peptides or proteins, including the peptide consisting of SEQ ID NO: 6827 have been shown to elicit an immune response that correlates with tumor clearance. Just as one cannot predict whether a peptide consisting of SEQ ID NO: 6827 can be used in the specific manner asserted, one cannot predict whether the multitude of other peptides and proteins comprising SEQ ID NO: 6827 can be used accordingly. Short of making each and every one of the peptides or proteins, or the compositions thereof, which are encompassed by the claims, and empirically determining whether the peptide binds HLA-A2.1 and is capable of stimulating CTL clones that effectively lyse prostate tumor cells to provide tumor clearance, the skilled artisan could not make and use the claimed invention.

If the claimed invention cannot be used in the specific manner asserted, the need to identify a use for the claimed invention falls into the realm of undue experimentation.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

In deciding *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970), the Court indicated the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. "Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001, 1005 (CA FC 1997).

Thus, the overly broad scope of the claims would merely serve as an invitation to one skilled in the art *to identify*, as indeed Applicant has argued, a peptide or protein consisting of, or comprising the amino acid sequence of SEQ ID NO: 6827, which

capable of stimulating an immune response that correlates with tumor clearance; yet, defining a substance by its principal biological activity amounts to an alleged conception having no more specificity than that of a wish to know the identity of any material with that biological property. See *Colbert v. Lofdahl*, 21 USPQ2d 1068, 1071 (BPAI 1991).

8. The rejection of claims 124, 125, 127, 131, 135-137, 139, 215, and 230-233 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the following reasons, originally set forth in section 15 of the previous Office action beginning at page 15:

(a) Claims 124-126, 131, 135-137, 139, 215, and 230-233 are indefinite because the claim depend from claim 114, which is drawn to a peptide consisting of the amino acid sequence of SEQ ID NO: 6827. A peptide, such as the peptide of claim 114, cannot further comprise a T helper peptide because the peptide of claim 114 consists of the amino acid sequence SEQ ID NO: 6827. Similarly, the peptide of claim 114 cannot further comprise one or more spacer molecules, a lipid, one or more other isolated peptides linked by one or more spacer molecules or by one or more spacer amino acids because, again, the peptide of claim 114 consists of the amino acid sequence SEQ ID NO: 6827.

At page 23 of the amendment filed December 17, 2004, Applicant has traversed this ground of rejection.

Applicant's argument has been carefully considered but not found persuasive for the following reason:

Applicant has argued the claims should be interpreted to read on the peptide of claim 114 and something else, since, for example, claims 124, 125, and 127 recite that the peptide of claim 114 is "linked to" a T helper peptide, one or more spacer molecules, or a lipid. In response, claims 124, 125, and 127 are each drawn to "[t]he peptide of claim 114", not to anything else. This issue should be remedied by amending the claims to be drawn to the subject matter that is the invention. For example, the rejection of claim 124 could be overcome by amending the claim to read: A fusion protein

comprising the peptide of claim 114 and a T helper peptide, wherein the amino acid sequence of the peptide of claim 114 and said T helper peptide are linked.

(b) Claims 131 and 137 are vague and indefinite because the claims recite "carrier molecule". Because of the duality of the meaning of the term "carrier", the claims are ambiguous and the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter that Applicant regards as the invention.

At pages 22 and 23 of the amendment filed December 17, 2004, Applicant has traversed this ground of rejection.

Applicant's argument has been carefully considered but not found persuasive for the following reason:

The carrier molecules described at page 46, lines 24-33, are only exemplary. Moreover, the carrier molecules described at page 46, lines 24-33, are only exemplary of the types of carrier molecules described therein. Elsewhere, the specification describes aqueous carrier molecules, such a pharmaceutically acceptable excipient molecules. It is improper to read limitations into the claims, particularly where there is not guidance for selecting one limitation over another. Contrary to the Applicant's argument, the skilled artisan would not understand that claims 131 and 137 are limited to compositions comprising the peptide of claim 114 and a carrier molecule, as described at page 46, lines 24-33, as opposed to a composition comprising the peptide of claim 114 and an aqueous carrier molecule, such as a pharmaceutically acceptable excipient molecule. 35 U.S.C. § 112, second paragraph, requires claims to particularly point out and distinctly claim the subject matter that is regarded as the invention so that the artisan can know whether or not a given subject matter infringes those claims. Because of the duality of the meaning of the term "carrier", the claims are ambiguous and the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter that Applicant regards as the invention.

***Claim Rejections - 35 USC § 102***

9. The rejection of claims 130, 135-137, and 140 under 35 U.S.C. 102(b) as being anticipated by Van Etten et al. (*J. Biol. Chem.* **26**: 2313-2319, 1991), as evidenced by WO 94/20127 A, is maintained.

This ground of rejection is set forth in section 17 of the previous Office action mailed June 17, 2004.

At pages 24 and 25 of the amendment filed December 17, 2004, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Applicant has argued that the heteropolymer disclosed by the prior art (i.e., PAP) does not comprise a peptide having the amino acid sequence of SEQ ID NO: 6827 and different immunogenic peptides. The Examiner, however, disagrees. Claim 130 is drawn to a heteropolymer, which is a single molecule. Accordingly, because the heteropolymer is "of the peptide of claim 114 and at least one different immunogenic peptide", the claim is drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 6827 and additional amino acid sequences. The heteropolymer disclosed by the prior art has an amino acid sequence that comprises the amino acid sequence of SEQ ID NO: 6827 and further comprises other amino acid sequences, which differ from the amino acid sequence of SEQ ID NO: 6827. The other amino acid sequences of which the disclosed heteropolymer is composed are reasonably expected to be immunogenic because most peptides of other amino acid sequences, which are of at least about 5 amino acids in length, are expected to be immunogenic in at least one type of animal; moreover, it is possible to use even smaller peptides or fragments thereof to produce an immune response, if, for example, the peptide or fragment is conjugated to a carrier.

Additionally, Applicant has argued that the prior art fails to anticipate the claimed invention, since claim 135 has been amended to recite that the one or other peptides of which the composition is comprised are isolated. In response, claim 136, which depends from claim 135, recites, "wherein said peptides are linked by one or more spacer molecules"; and claim 139, which also depends from claim 135, recites, "wherein

said peptides are linked by one or more spacer amino acids". Therefore, claims 136 and 139 are specifically drawn to a composition comprising a single molecule and claims 135 and 137 necessarily encompass compositions comprising such single molecules; so, the one or more other peptides (i.e., amino acid sequences) of which the claimed composition is comprised are not necessarily "isolated" from the peptide (i.e., amino acid sequence) of SEQ ID NO: 6827. Accordingly, given the broadest reasonable interpretation in light of claims 136 or 139, claim 135 is drawn to a composition comprising a protein comprising the amino acid sequence of SEQ ID NO: 6827 and one or more other amino acid sequences, which differ from the amino acid sequence of SEQ ID NO: 6827 and which are linked by one or more "spacer molecules" or "spacer amino acids", such as PAP, which comprises the amino acid sequence of SEQ ID NO: 6827 and other amino acid sequences that are linked by still other amino acid sequences. Moreover, given that claims 136 and 139 are specifically drawn to a composition comprising a single molecule and that claims 135 and 137 necessarily encompass compositions comprising such single molecules, the still other amino acid sequences that link the amino acid sequence of SEQ ID NO: 6827 and the one or more other amino acid sequences are reasonably considered the same as "spacer molecules" or "spacer amino acids". So contrary to Applicant's assertion, the claimed subject matter is not distinguished from polypeptide disclosed by the prior art.

***Claim Rejections - 35 USC § 103***

10. The rejection of claims 130, 135-137, 139, and 140 under 35 U.S.C. 103(a) as being unpatentable over Van Etten et al. (*J. Biol. Chem.* 1991; **26**: 2313-2319) in view of Zsebo (*J. Biol. Chem.* 1986; **261**: 5858-5865), as evidenced by WO 94/20127 A and Ostanin et al. (*J. Biol. Chem.* 1994; **269**: 8971-8978), is maintained.

This ground of rejection is set forth in section 19 (misnumbered 17) of the previous Office action mailed June 17, 2004, beginning at page 17.

At pages 25 and 26 of the amendment filed December 17, 2004, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Applicant has argued that the prior art does not teach or suggest every element of the claimed invention, since claim 135 has been amended to recite that the one or other peptides of which the composition is comprised are isolated. In response, claim 136, which depends from claim 135, recites, "wherein said peptides are linked by one or more spacer molecules"; and claim 139, which also depends from claim 135, recites, "wherein said peptides are linked by one or more spacer amino acids". Given the broadest reasonable interpretation in light of claims 136 or 139, claim 135 is drawn to a composition comprising a polypeptide, including a fusion protein comprising the amino acid sequence of SEQ ID NO: 6827 and one or more heterologous amino acid sequences, which are linked by one or more spacer molecules, such as a fusion protein comprising PAP, a spacer, and prepro-α-factor.

***Double Patenting***

11. The rejection of claims 114, 121-128, 130, 131, 133-137, 139, 140, and 215 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 and 23-25 of copending Application No. 10/168,507 is maintained.

This ground of rejection is set forth in section 21 (misnumbered 19) of the previous Office action mailed June 17, 2004, beginning at page 20.

At page 26 of the amendment filed December 17, 2004, Applicant states that this ground of rejection is traversed and requests that the issue be held in abeyance until such a time the conflicting claims may be patented.

***Conclusion***

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
March 18, 2005

LARRY R. HELMS, PH.D
PRIMARY EXAMINER